DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry: Changes to an Approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Changes to an "Approved NDA or ANDA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 1999 (64 FR 65716), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under the emergency processing provisions of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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OMB has now approved the collection of information and has assigned OMB control number 0910-043 1. The approval expires on May 3 1, 2000. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 22, 1999

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

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